

## REMARKS

### I. Rejection under 35 U.S.C. 101

Claims 1, 3 to 5 and 7 were rejected under 35 U.S.C. 101 because the invention was directed to non-statutory subject matter.

Claims 1 to 5 and 7 have been canceled, obviating the rejection under 35 U.S.C. 101. New claim 9 replaces the canceled claims 1 and 2. Since new claim 9 includes the subject matter of claim 2 it avoids the rejection under 35 U.S.C. 101. New claim 9 is also drafted to avoid the rejection for indefiniteness.

New claim 9 clearly claims a **special mixture** that is "made by the hand of man" and that is useful. Thus the subject matter of claim 9 qualifies as statutory subject matter under 35 U.S.C. 101 and MPEP 2105. The special mixture of claim 9 comprises eight particular bacterial species identified in claim 9, carbon sources that act as a nutrient, for example cellulose or hemi-cellulose (dependent claim 11) and electron acceptors including inorganic salts (preferably including nitrates as claimed in dependent claim 10). Page 7, last four lines, of applicants' specification, explains that when the very low levels of oxygen initially present are used up during the growing of the special mixture of bacteria and fungi the microbes respire using the inorganic salts, e.g. in a closed environment (tank) as described on page 13 of the applicants' specification.

The resulting mixture comprises the bacterial and fungi species and classes of chemical compounds, e.g. inorganic salts, set forth in claim 9. The

claimed mixture is useful because it is the effective agent in a method of deodorizing and digesting organic waste, such as sewage.

The specification identifies examples of the various fungi and bacteria species by ATCC deposit number so that individuals in different countries can easily obtain examples of the various bacterial species of claim 9 from the ATCC. The various bacterial species cooperate, as explained in the paragraph running from page 10 to 11 in applicants' specification, to obtain the objectives of the invention, decomposing and/or purifying organic waste when employed in methods for doing that.

During the growing of claim 9 the microbes numbered 1, 2, 3 and 6 on page 9 of the specification secrete mucous fluid which contains enzymes that digest the organic matter leaving the by-products (new claim 14). The microbes numbered 4 and 5 decompose these by-products into inorganic elements, which may be digested by the microbes numbered 7 and 8.

None of the individual microbes of the mixture of claim 9 are "new" microorganisms that require deposit in the ATCC. This should be clear because the exemplary strains mentioned in the specification already have ATCC deposit numbers. Thus applicants' should not be required to deposit any microorganism with the ATCC. The situation regarding *Methylosinus trichosporium* was confused by providing an incorrect ATCC deposit number and will be explained in further detail hereinbelow.

The resulting fungi and bacterial group mixture is different from the mixture obtained under completely anaerobic conditions of the type that are used

by the Higa reference, for example. The special microbe mixture of claim 9 with its unique composition and properties results, e.g. when organic waste material with carbon sources as nutrients and inorganic salts that promote respiration are aerated in a closed environment (experimental tank) with a level of dissolved oxygen of 1 ppm or less.

Thus the human activity that results in the claimed product, namely the mixture of the bacteria and fungi, is e.g. aeration under controlled conditions in a closed environment so that the oxygen concentration is maintained at 1 ppm or less. This particular claimed mixture would not be produced in nature without this human intervention. Furthermore these growth conditions differ from completely aerobic conditions, which do occur in nature, and also from completely anaerobic conditions at a pH of 3.0 to 5.0, like those of the Higa reference.

For the foregoing reasons it is respectfully submitted that new claims 9 to 14 should not be rejected under 35 U.S.C. 101.

## II. Indefiniteness Rejection

Claims 1 to 5 and 7 were rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.

Claims 1 to 5 and 7 were canceled, obviating their rejection on these grounds. New claims 9 to 14 have been drafted to provide a claim wording that does not suffer from the deficiencies of claims 1 to 5 and 7 that led to their rejection for indefiniteness.

Claims 1, 5 and 7 were rejected because the maximum level for oxygen in the environment during growth was not precisely specified. New claim 9 limits the oxygen level in the growth environment to 1 ppm or less. Basis for this change is found on page 9, line 17, and page 13, line 6, for example. The term "essentially" was used in the English translation of the Japanese disclosure was intended to mean "about". Both these latter terms are acceptable in claims, at least under some circumstances (MPEP 2173.05 (b)).

The term "predominant" is no longer used in the claims. The explanation of the manner in which the types of microbes cooperate in the section regarding the rejection under 35 U.S.C. 101 should explain why the mixture of microbes is required for optimum results during treatment of organic waste.

The term "cellulose substance" is no longer used in the claims. Instead examples of the "cellulose substances" from page 8, about line 22.

It is respectfully submitted that new claims 9 to 14 should not be rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.

### III. Rejection of Claim 2 under 35 U.S.C. 112, first paragraph

Claim 2 was rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Claim 2 was also rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim 2 has been canceled but the eight species of fungi and bacteria of claim 2 have been included in new independent claim 9. However new

independent claim 9 should not be rejected for lack of enablement or failing to comply with the written description requirement.

None of the individual microbes of the mixture are "new" microorganisms that require deposit in the ATCC. Thus applicants' should not need to deposit any microorganism with the ATCC.

Unfortunately the ATCC deposit number for *Methylosinus trichosporium* given in the disclosure was incorrect. The correct ATCC deposit number, 49242, has been inserted in the specification by the above changes. A sheet from the ATCC web site accompanies this amendment to show that this ATCC deposit number is the correct number for this species.

The ATCC deposit numbers designate particular strains of bacterial species, which have different properties. For example, ATCC lists 11 different strains of *Flavobacterium johnsoniae* as shown by the attached list obtained from the ATCC web site. Some of these strains are, in fact, deposited under different genera. For example some of the *Flavobacterium johnsoniae* are deposited as *Flexibacter columnaris*.

Names, such as *Flavobacterium johnsoniae*, designate bacterial strains. According to one Internet web site (print out accompanies this amendment) states that

"a bacterial species may be regarded as a collection of strains that share many features in common and differ considerably from other strains. One strain of a species is designated as the type strain; this strain serves as the name-bearer strain of the species and is the permanent example of the species, i.e. the reference specimen for the name. The type strain has great importance for classification at the species level, because a species

consists of the type strain and all other strains that are considered to be sufficiently similar to it as to warrant inclusion with in the species.”

New claim 9 claims a mixture of eight different species of fungi and bacteria. The ATCC deposit numbers given in the specification and original claims only give examples of individual strains of the particular claimed species, which were identified experimentally as part of the grown mixture of fungi and bacteria (p. 13 of the specification). The specification has been amended to state that the ATCC deposit numbers only designate exemplary strains of the microbe species of the invention. The ATCC deposit numbers are no longer used in the claims, because the important symbiotic relationships between the bacteria are established not for particular strains, but with any strain of the claimed species recited in claim 9. For example, it is especially important that some species secrete a mucous fluid containing enzymes that digest the organic waste material to produce by-products and other species digest and process the by-products as explained on page 10 and 11 of the applicants' specification and claimed above in new claim 14.

The fungi and bacterial group mixture as claimed in claim 9 was produced by a method performed in Japan. Not only that the species of bacteria and fungi found in the claimed mixture are available in Japan. The ATCC deposit numbers of strains of the claimed species were only provided, because the ATCC is an international depository organization that is approved under the Budapest Treaty. Thus it is easy for individuals and organizations around the world to obtain exemplary strains for the various species using protocols from the ATCC.

However strains of the claimed species of claim 9 are available in Japan from the following organizations known to the applicants:

1. *Mucor indicus* (IFM41561, Research Center for Pathogenic Fungi and Microbial Toxicoses, Chiba University, Japan);
2. *Myxococcus* sp., (This is a common microbe existing all over the soil, e.g. *Myxococcus xanthus* is well known, but it is not on deposit in Japan);
3. *Flavobacterium johnsoniae*, (IFO15970, Institute for Fermentation, Osaka, Japan) ;
4. *Pseudomonas alcaligenes*, (JCM 5967, Japan Collection of Microbes, RIKEN);
5. *Klebsiella ornithinolytica*, (JCM 6096, Japan Collection of Microbes, RIKEN);
6. *Bacillus licheniformis*, (JCM 2505, Japan Collection of Microbes, RIKEN);
7. *Bosea thiooxidans*, (GTC1597, Department of Microbiology, Gifu University School of Medicine, Japan); and
8. *Methylosinus tricosporium*, (NCIMB11131, National Collections of Industrial and Marine Bacteria, Ministry of Agriculture, Fisheries and Food, Branch of Japan).

Applicants have stated in communications to us that the inventive method for making the claimed mixture was performed in Japan and that the species in the mixture as now claimed in claim 9 were identified using the nucleotide

sequence of ribosomal 18S RNA in the case of the fungi. The bacteria were identified using the corresponding nucleotide sequence of ribosomal 16S RNA. For example, see page 13 of applicants' specification.

In other words, to identify the microbes that appeared during the growing of claim 9 the DNA sequence of each microbe was determined by analysis, then a search of the nucleotide sequence database (e.g. DDBJ) was conducted for the microbe which had the most similar nucleotide sequence to the nucleotide sequence determined by the DNA analysis and finally the ATCC database was searched for the strain identified by an ATCC deposit number that was most similar to the microbe identified in the search of the nucleotide sequence database.

In fact, the advantages and benefits of the claimed invention are due to the symbiotic relationships between the bacteria and fungi species listed in claim 9, as set forth in claim 14 and described in applicants' specification. Thus it is expected that the claimed mixture of the strains designated with the exemplary ATCC deposit numbers or the mixture of different strains, but the same species, obtained from the Japanese depository institutions would have the same beneficial properties for deodorizing and digesting organic waste material.

Claim 9 claims a mixture of fungi and bacterial species which is limited to containing the eight recited species of bacteria and fungi and a carbon source acting as a nutrient and at least one inorganic salt. Since strains of all the species of bacteria and fungi listed in claim 9 are available in at least one depository, one skilled in the art would be clearly enabled to make and use



examples of this claimed mixture in a reproducible manner. It should be noted that one skilled in the art would not be limited to the exemplary embodiment of the claim 9 mixture that is claimed in claim 13 in which the mixture is produced by aeration of organic waste material in a closed environment in which the oxygen concentration is limited to 1 ppm or less. However the experimental results of the applicants reported in the specification have shown that examples of the embodiment claimed in dependent claim 13 contain the eight species of microbe recited in claim 9.

The written description specification clearly supports the new claim 9 that claims a mixture of eight fungi and bacterial species, because one skilled in the art would understand that the ATCC deposit numbers refer to strains, but that the invention is not limited to individual strains. One would expect that mixtures of different strains of the eight species would have similar advantageous and beneficial properties and that strains deposited in the ATCC were exemplary and listed for convenience.

For the foregoing reasons it is respectfully submitted that none of the new claims 9 to 14 should be rejected under 35 U.S.C. 112, first paragraph, for lack of enablement or failure to comply with the written description requirement.

#### IV. Objections to the Specification and Claims

The disclosure was objected to because the scientific names in the specification were not properly formatted.

Changes have been made in accordance with 37 CFR 1.121 to provide properly formatted names for microorganisms and to correct spelling of names and terms.

Also the ATCC deposit numbers only designate exemplary strains of the particular fungi and bacterial species used by the applicants. The specification has been amended to indicate that they designate exemplary strains only.

Withdrawal of the objections to the claims and specification is respectfully requested.

#### V. Anticipation Rejection

Claims 1, 3 to 5 and 7 were rejected as anticipated under 35 U.S.C. 102 (b) by Higa, in light of Kikuth, et al.

Claims 1, 3 to 5 and 7 have been canceled, obviating their rejection as anticipated.

New claims 9 to 14 are limited to a mixture of eight particular bacterial species that is neither disclosed in Higa or Kikuth.

For the foregoing reasons it is respectfully submitted that new claims 9 to 14 should not be rejected under 35 U.S.C. 102 (b) based on Higa, US 5,591,634, and Kikuth, et al, US 4,793,929.

#### VI. Obviousness Rejection

Claims 1 to 7 were rejected as obvious under 35 U.S.C. 103 (a) over Higa, in view of Kikuth, et al, and Miyaji. First, it is assumed that this rejection applies

to claims 1 to 5 and 7 since claim 6 was withdrawn from consideration because of a restriction and election requirement.

Claims 1 to 5 and 7 have been canceled, obviating the rejection under 35 U.S.C. 103 (a). New claims 9 to 14 have been added. New claim 9 contains features from canceled claims 1 and 2 and has been explained above.

Claim 9 claims a mixture of eight different bacterial species grown under special conditions by aeration but with the dissolved oxygen concentration equal to or less than 1 ppm, preferably in organic waste material.

The issue here is not whether or not the growing method by which the mixture is made is unobvious, but whether or not the claimed mixture itself is unobvious.

The claimed mixture of claim 9 is limited to a mixture of eight individual species, namely *Mucor indicus*, *Myxococcus sp.*, *Flavobacterium johnsoniae*, *Pseudomonas alcaligenes*, *Klebsiella ornithinolytica*, *Bacillus licheniformis*, *Bosea thiooxidans* and *Methylosinus tricosporium*. According to claim 8 all eight of these species must be present in all embodiments of the claimed mixture and they must have been grown under special conditions that do not correspond to aerobic or anaerobic conditions. These growth conditions are as follows:

- (a) aerating but keeping the level of dissolved oxygen at 1 ppm or less;
- (b) the presence of inorganic salts that can be used for respiration by the microbes.

During the growth individual groups of the microbes cooperate with each other as claimed in claim 14 and explained above and in the specification to

produce a special mixture of enzymes, which makes the claimed mixture particularly useful for deodorizing and decomposing organic waste.

The claimed method of Higa includes using a mixture of at least five species of microorganism including actinomycetes, phototropic bacteria, lactic acid bacteria, mold fungi and yeast (column 3, lines 25 to 35). Individual examples of these microorganisms are listed in column 3, line 66, to column 4, line 26 and claim 1 of Higa. All five groups of microbes are required in all embodiments of Higa. Only one species listed in claim 9 has a genera that is the same as a single species in the list of bacteria and fungi species in columns 3 and 4 of the reference!

It is respectfully submitted that a mixture of eight different species of bacteria cannot be *prima facie* obvious from another mixture containing five entirely different bacterial species.

Furthermore applicants' eight microbe species are grouped into three groups according to their ability to secrete mucous containing digestive enzymes, their ability to consume by-products of the digestion and to further decompose into inorganic substances as claimed in claim 14 and described on pages 10 and 11 of applicants' specification. In contrast, the mixture of microbes of Higa (column 3) is divided into five groups: actinomycetes, phototropic bacteria, lactic acid bacteria, mold fungi and yeast. Applicants mixture does not include yeast species and has no species in common.

The required types of microbes in the instant claim 9 and Higa are different because Higa describes a growth process that takes place under airtight

or anaerobic conditions at a pH of 3.0 to 5.0 (claim 1). The process for making the mixture of claim 9 takes place by aeration but with the dissolved oxygen concentration maintained at 1 ppm or less.

Again the question is not whether the mixtures both act to digest or decompose organic waste under their respective conditions or not, the question is whether or not the very different mixture of eight bacterial species grouped into bacterial species types with fundamentally different properties of claim 9 is prima facie obvious from a mixture of five entirely different bacterial species. Applicants respectfully submitted that it is not reasonable to reach a conclusion that any of claims 9 to 14 are obvious from the disclosures in Higa.

Kickuth, et al, has only been cited for the understanding that nitrogen compounds are converted to nitrate in similar organic waste digestion processes (column 2, line 60 and following and column 10 lines 12 to 45). Furthermore the process employed in Kickuth, et al, is entirely aerobic (see claim 1, column 3, lines 5 to 12). Kickuth, et al, carry out a so-called activated sludge treatment method.

Thus one skilled in the art would be unlikely to consult Kickuth, et al, for improvements in the methods of Higa, because Higa discloses a completely anaerobic process for treating organic waste material while Kickuth, et al, discloses an aerobic process.

Miyaji teaches a treatment method comprising mixing activated sludge and organic waste and then adding sodium nitrate solution to the mixture. The microbes mentioned in Miyaji are the denitrifying bacteria existing in the activated

sludge and differ from the microbes listed in claim 9, which appear under the entirely different conditions including aerating but maintaining dissolved oxygen concentration at 1 ppm or less.

Furthermore the Office Action does not provide any reasons why the secondary references, Kikuth, et al, and Miyaji, provide a hint or suggestion of the modifications of the disclosures of the five different classes of microbes according to claim 1 of Higa and the list of individual microbes therein that result in the eight different microbes species of claim 9 with entirely different characteristics according to e.g. claim 14. This sort of hint or suggestion is required for a valid rejection of claims 9 to 14 under 35 U.S.C. 103 (a) based on these references.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

"Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on as single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." *In re Kotzab*, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141


It is respectfully submitted that neither Higa alone nor Higa in combination with the secondary references provide a hint or suggestion of the fungal and bacterial group mixture claimed in applicants' claims 9 to 14.

For the foregoing reasons it is respectfully submitted that new claims 9 to 14 should not be rejected under 35 U.S.C. 103 (a) over Higa, in view of Kikuth, et al, and Miyaji.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

  
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